

SPL Advanced

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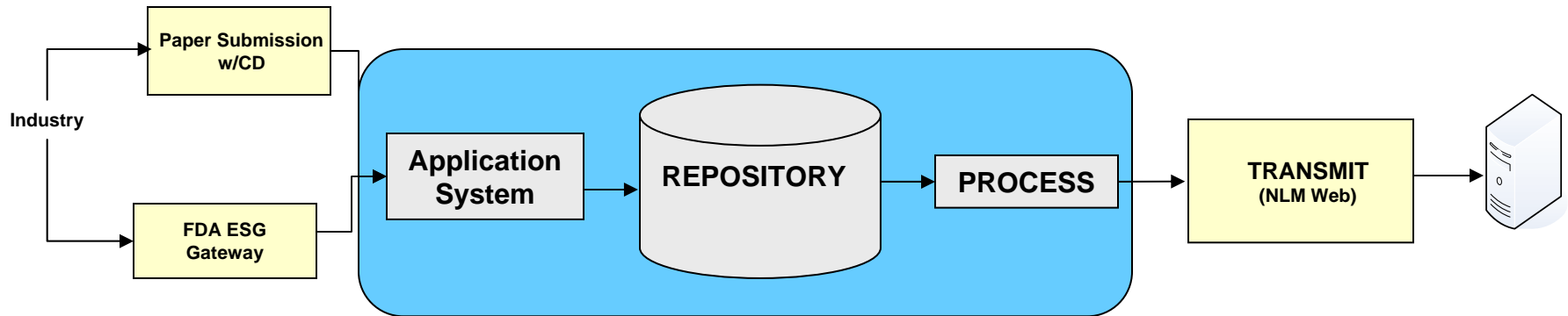


Data Usage

- Ensure your data is accurate
- Data transmitted to the public will be viewed by millions (DailyMed received 10 million hits per month)
- Other SPL authors (repackers & relabelers) may use your data

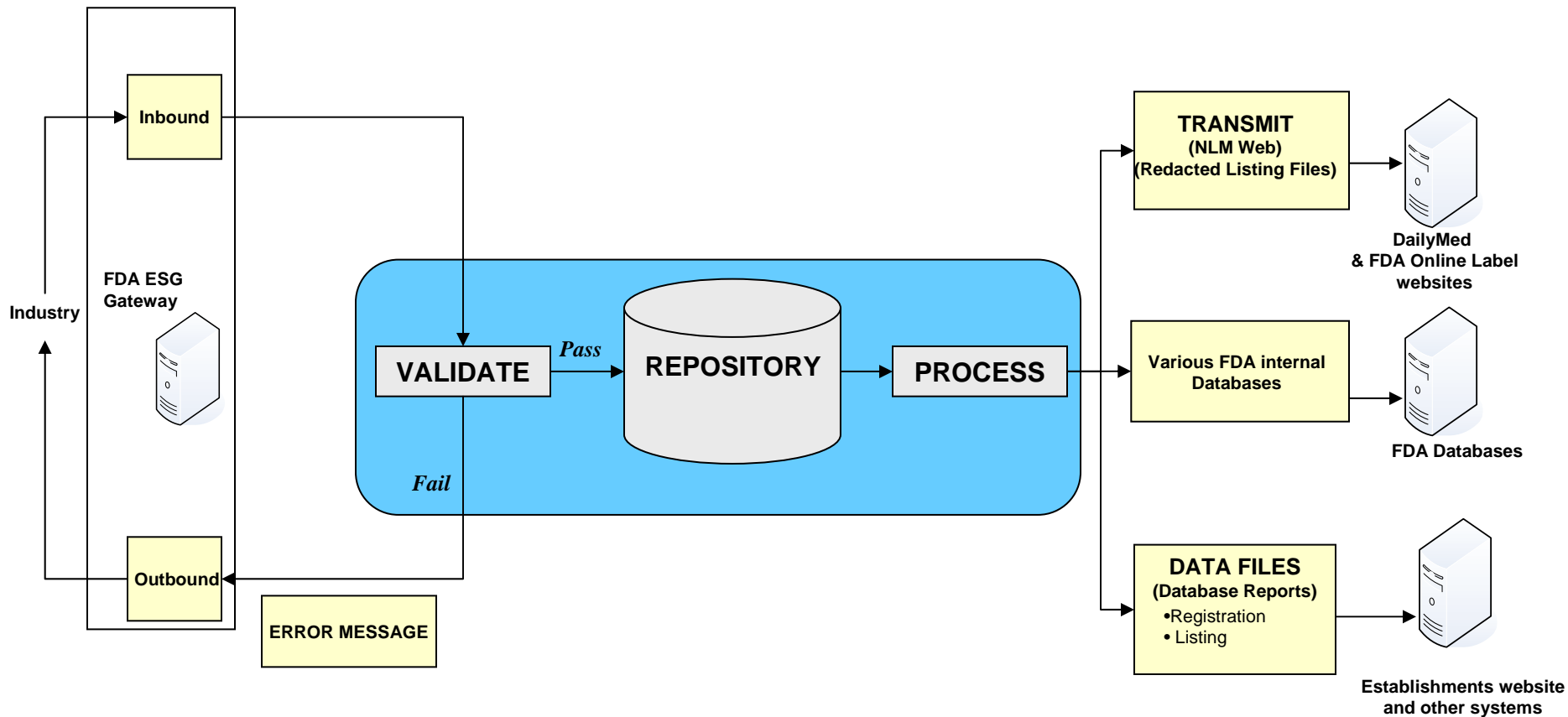
ELIPS - Old Process

October 2005 – May 2009

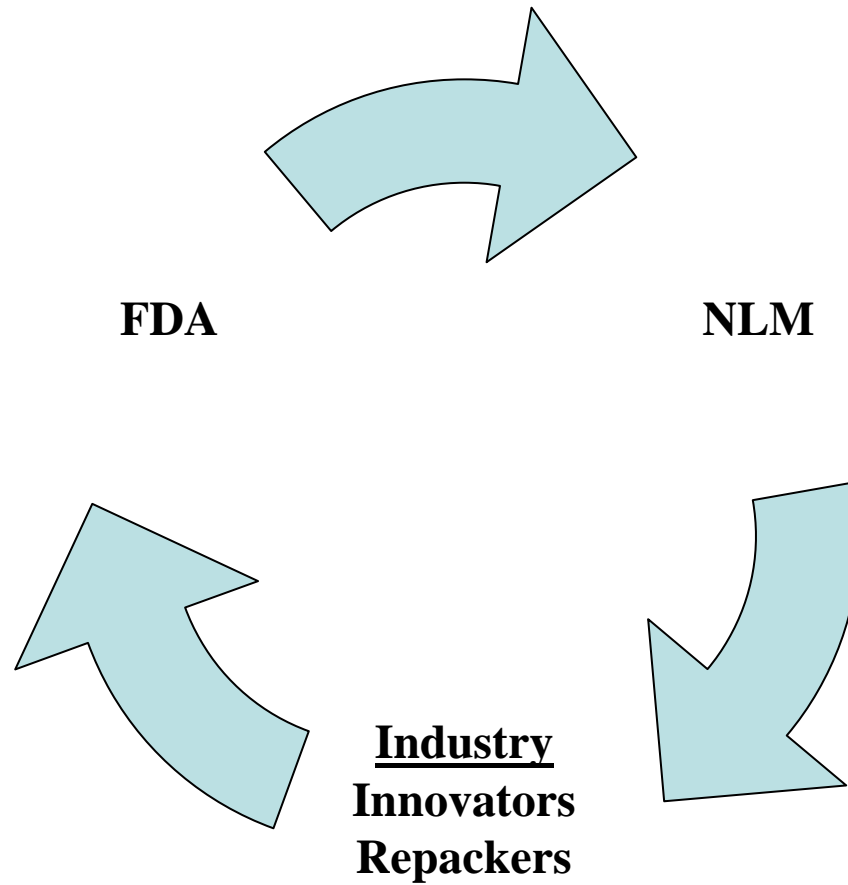


Data Exchange Service/eLIST

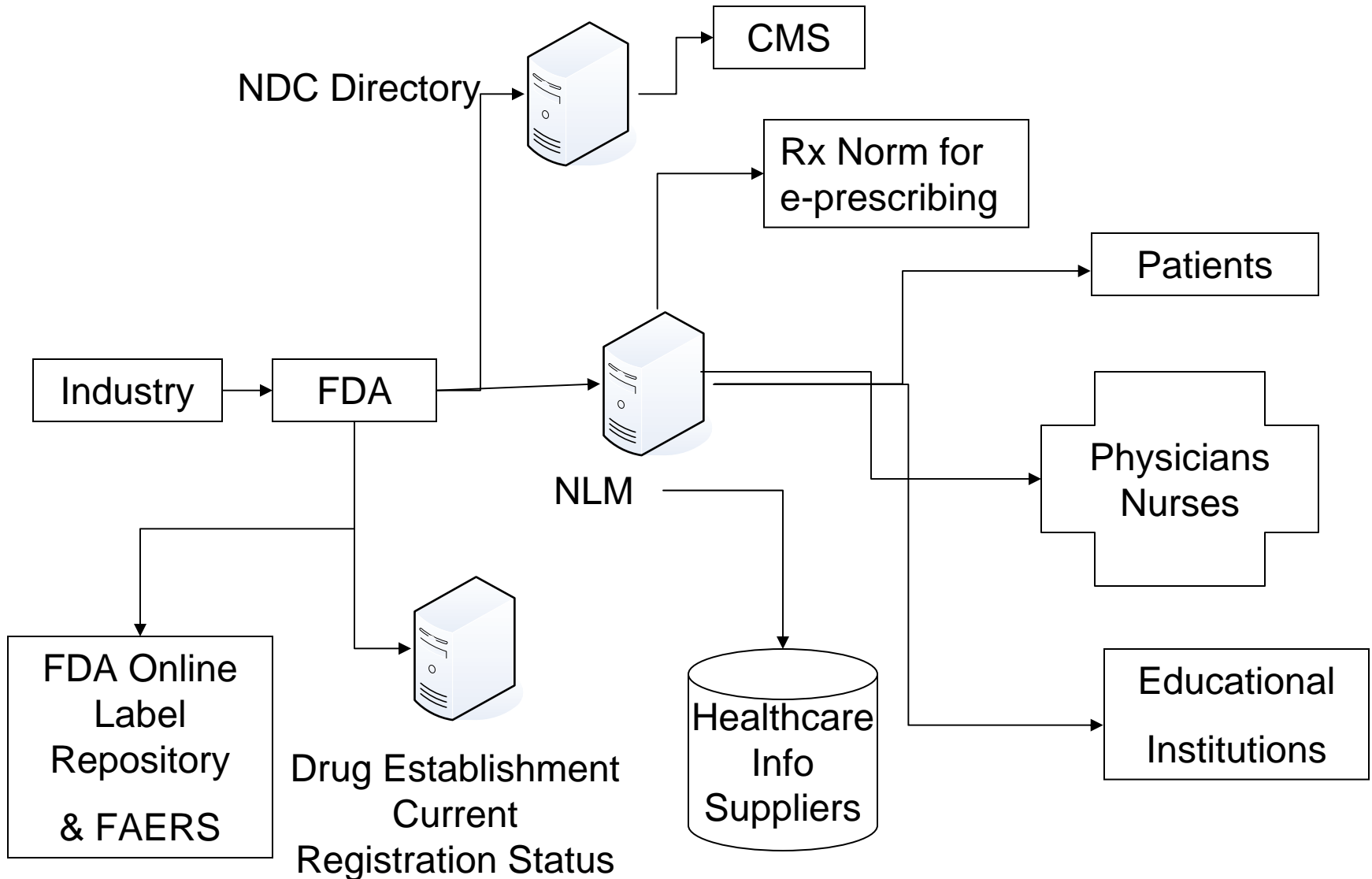
June 2009 – Present



Exchanging SPL Data

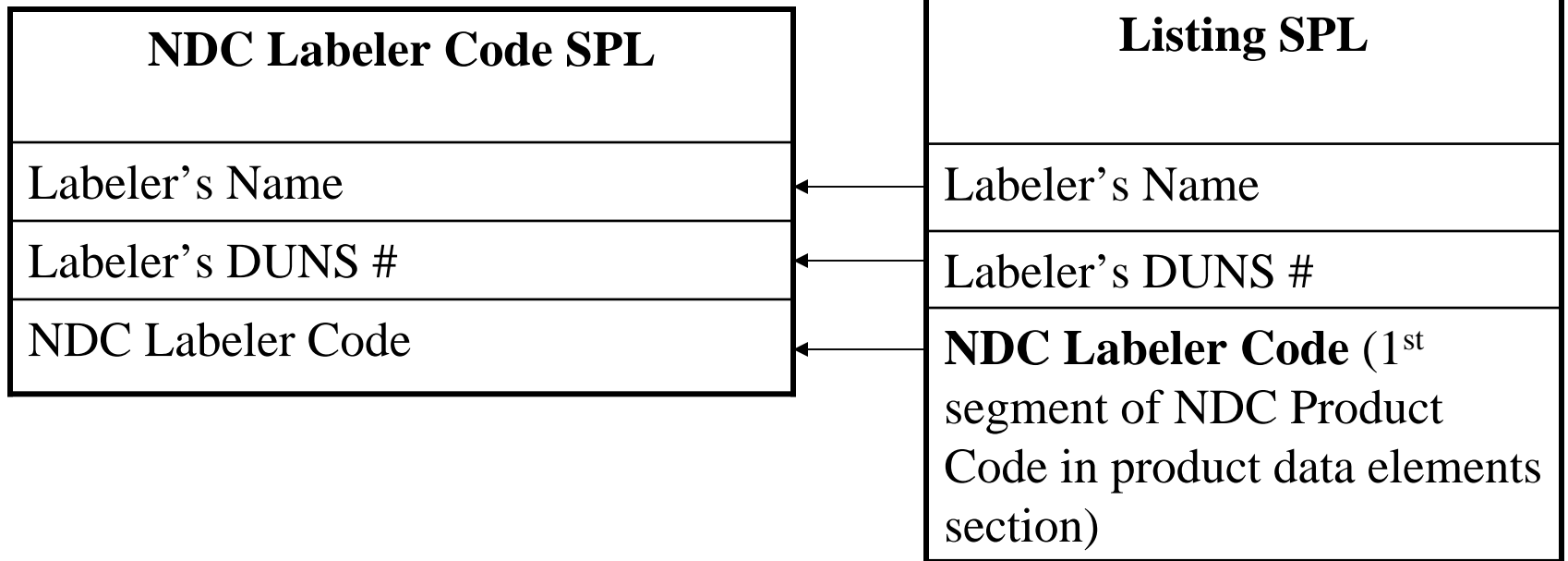


Data Sharing

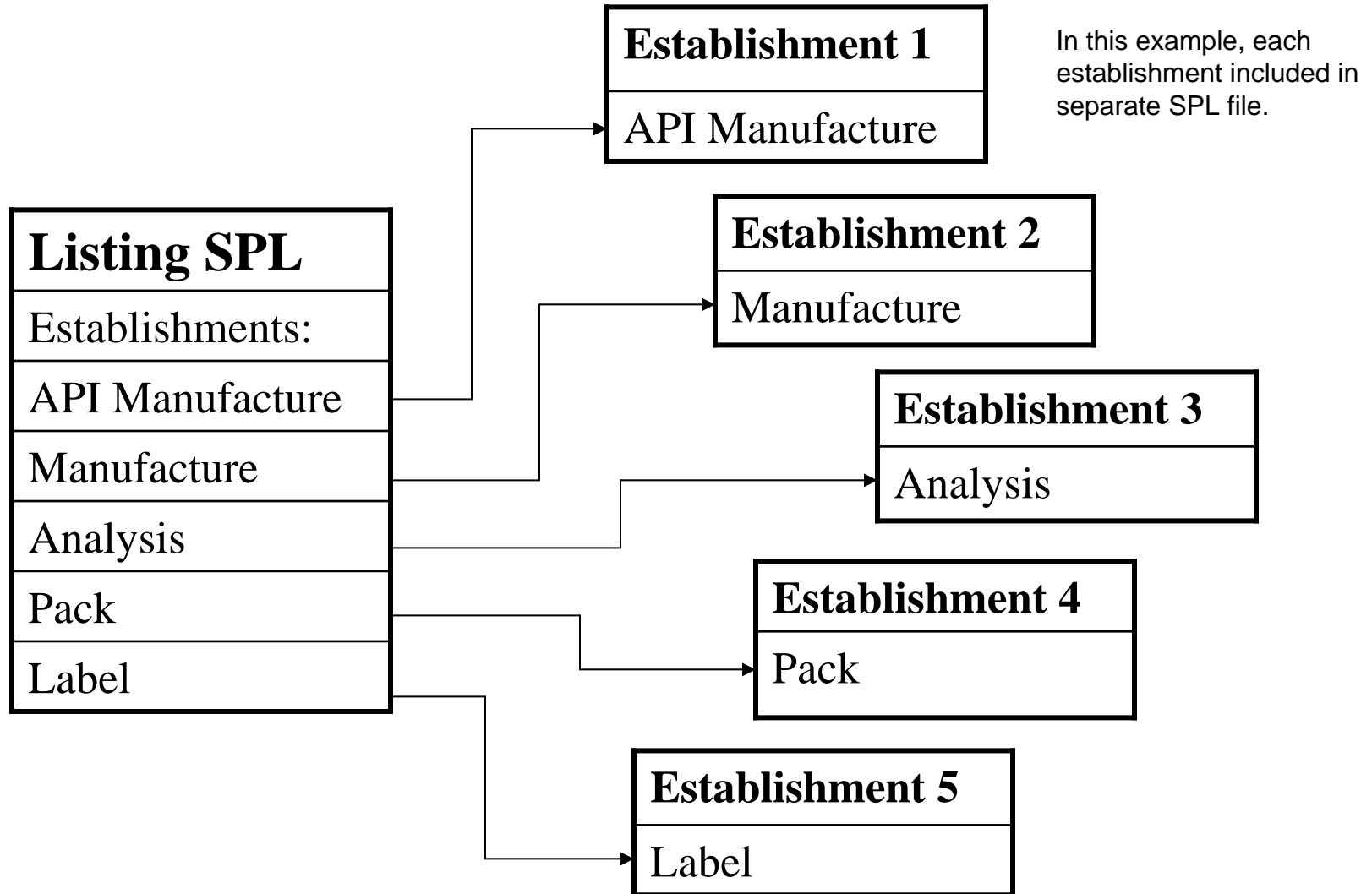


Data Relationships in SPL

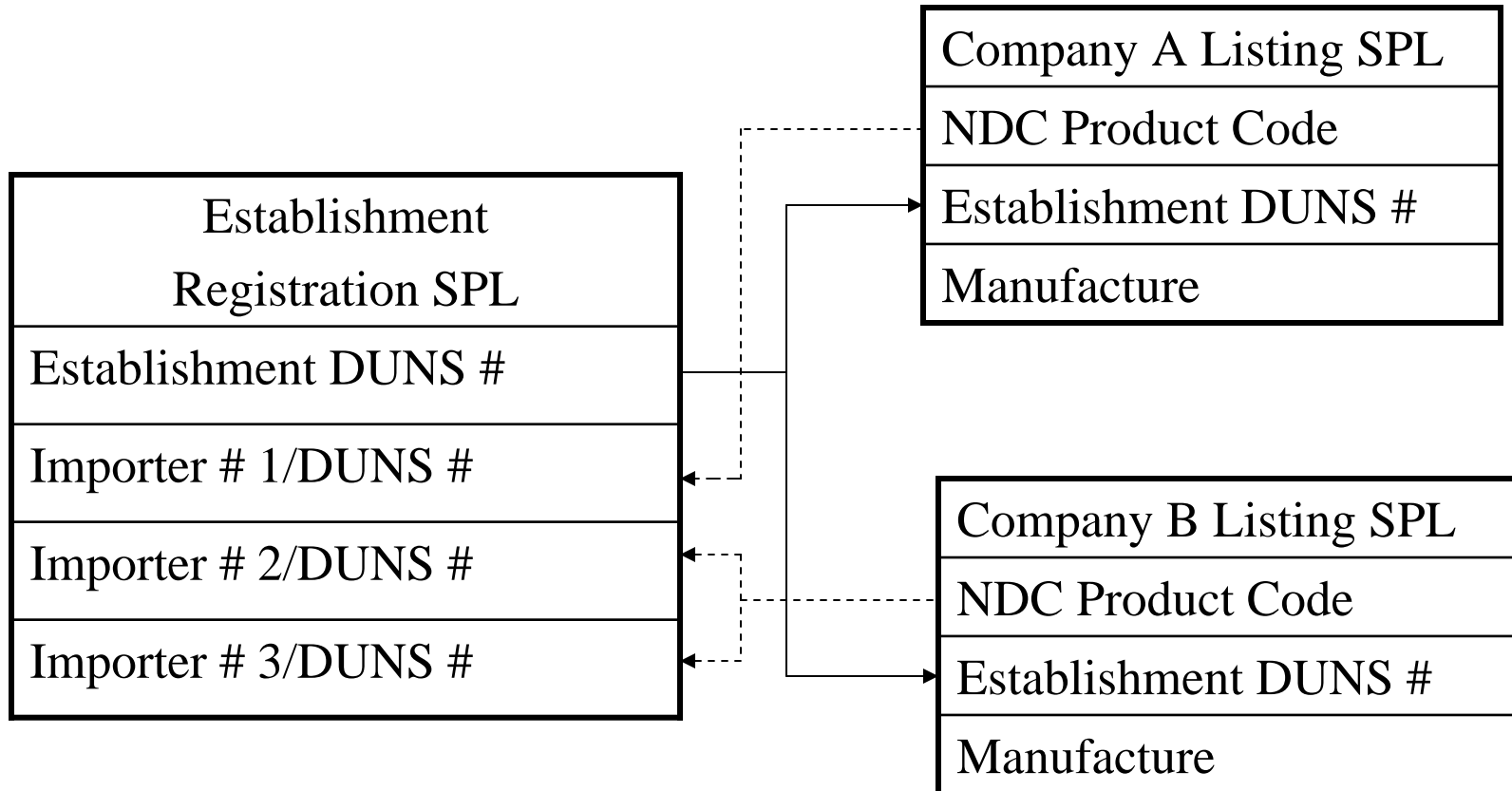
Labeler Code to Listing File



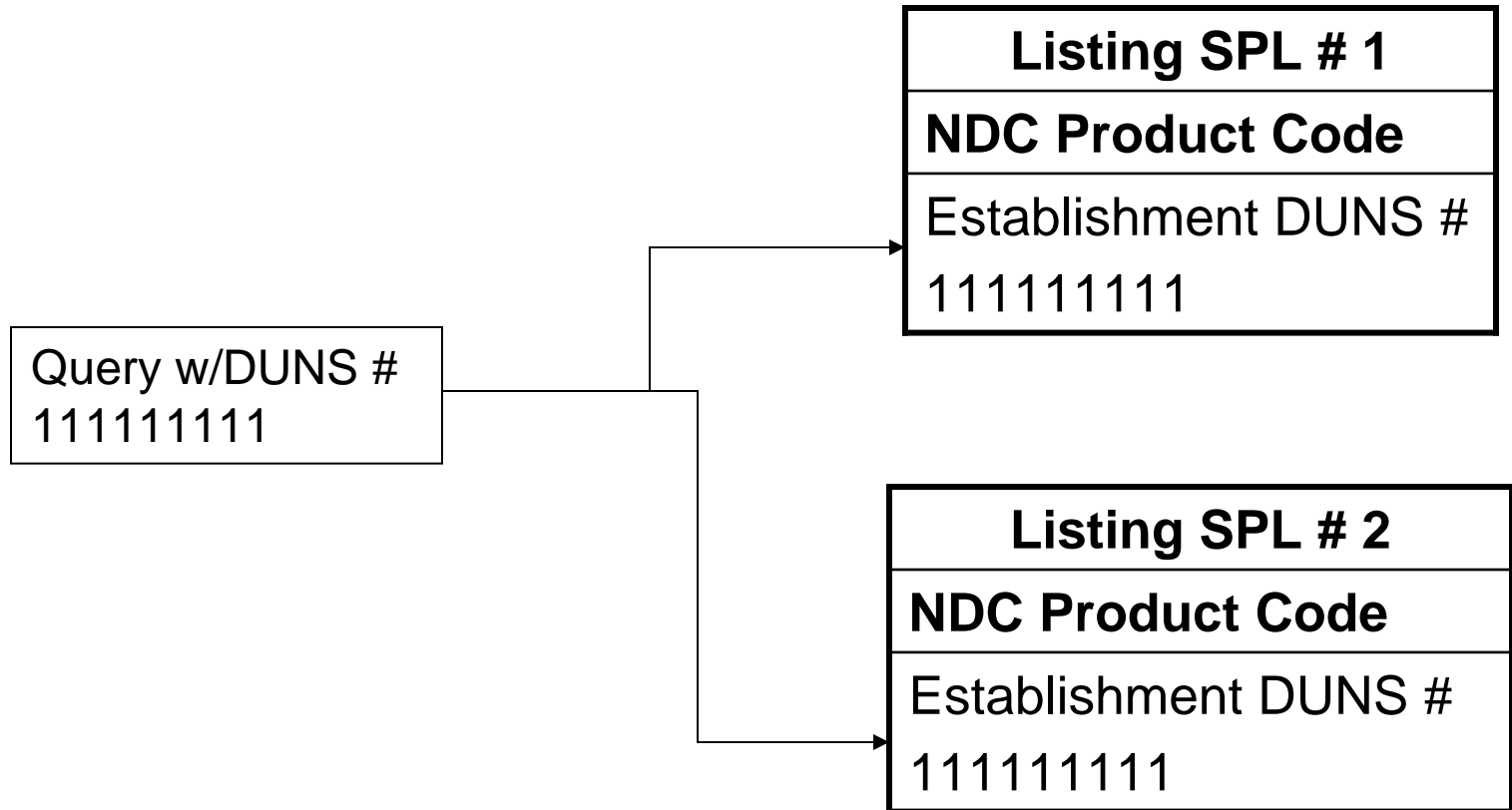
Listing Data & Establishment Data



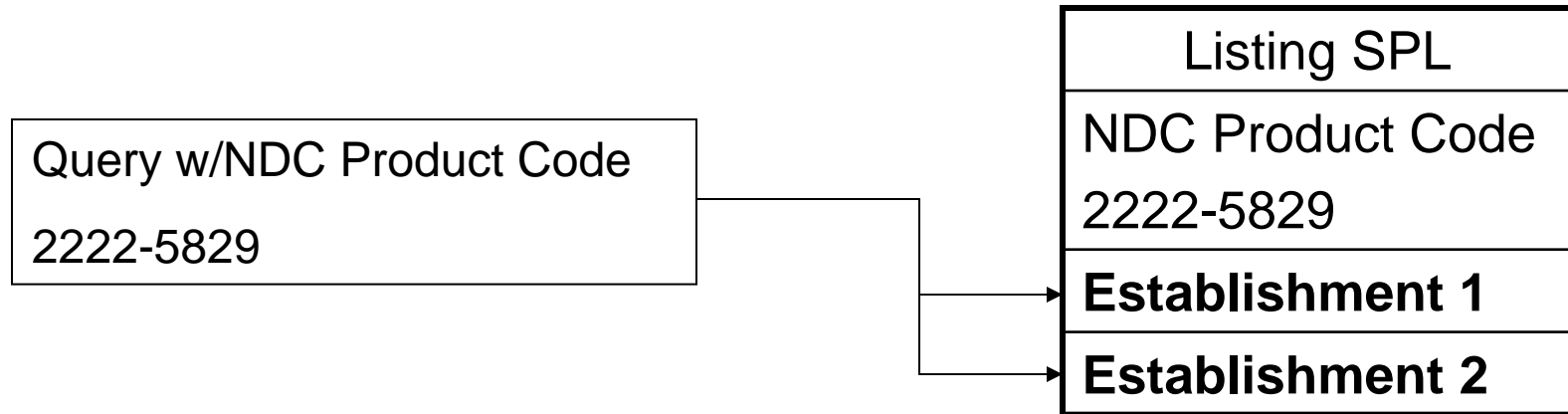
Product Link to Establishment & Importers



Query for Products Linked to an Establishment



Query for Establishments Linked to a Product



Updating Data

Updating Data - Labeler Code

- Revise previously submission valid version of NDC Labeler Code
- RETAIN original setID
- RETAIN NDC Labeler Code
- Change information requiring update
 - Labeler Name
 - Contact's name and address
 - Document tracking information (except setID)

Drug Establishment Ownership Changes - Owner/Operator of Multiple Drug Establishment

- To indicate transfer of ownership for one of many drug establishments in a previously submitted Establishment Registration (ER) SPL document
 - Remove the drug establishment from the previous owner's ER SPL document and submit updated file
 - Add the drug establishment to the new owner's ER SPL document and submit updated file (retain original setID)

Drug Establishment Ownership Changes - Owner/Operator of Only One Drug Establishment

- To indicate transfer of ownership for one drug establishment submitted Establishment Registration (ER) SPL document when registrant has only one drug establishment:
 - Submit Out of Business Notification SPL
 - Add the drug establishment to the new owner's ER SPL document and submit updated file (retain original setID)

Current Registration Year

- Subset of data from Establishment Registration SPL file populates the Drug Establishment Current Registration Site website
- Current registration year is extracted from effective time field of Establishment Registration SPL document
- Example: effective time 20120105
- Current registration on web: 2012

Register Only Your Drug Establishments

- Register your drug establishments only.
- Do not register other registrants' drug establishments via a test or official Establishment Registration SPL document

Discontinuing Products

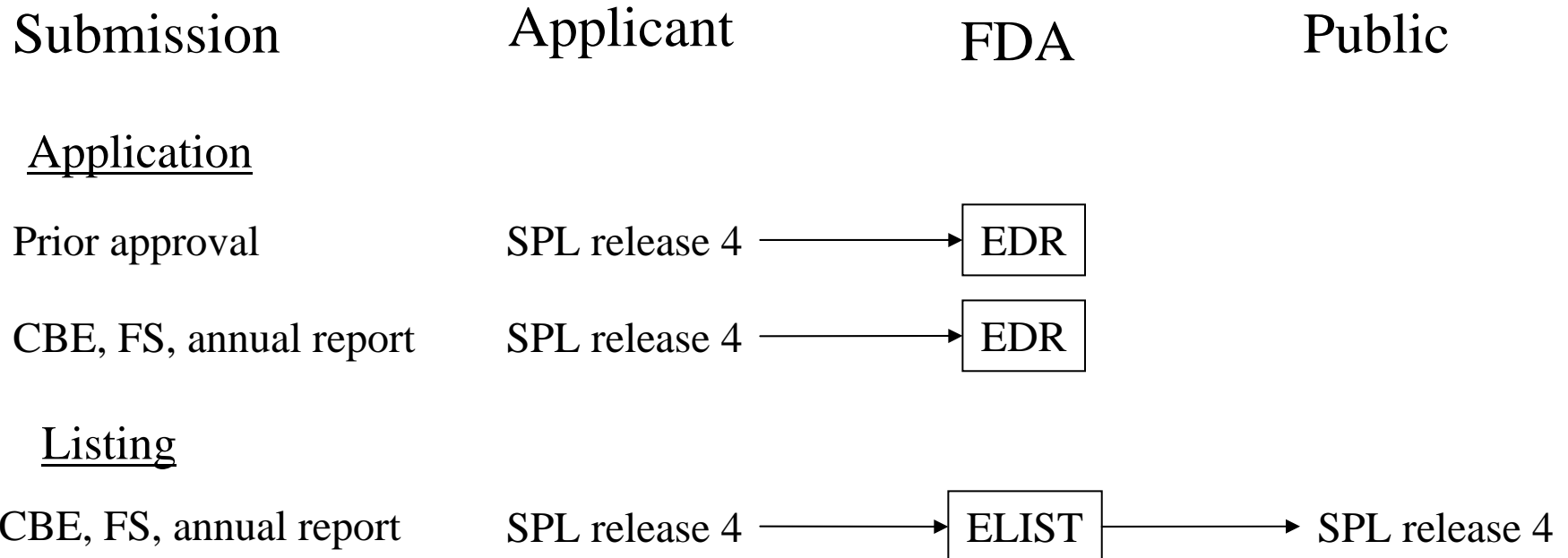
- Update previously submitted SPL document to include marketing end date and change marketing status to “completed” for the drug which is to be discontinued.
- After drug is discontinued, update file to remove information about drug product.
- Do not change information for other existing drug products
- If the product is not an approved drug product regulated by CBER and CDER, the SPL used to discontinue drug may be the first one submitted for the products to be discontinued.

CBER & CDER Application Product SPL Submission Process

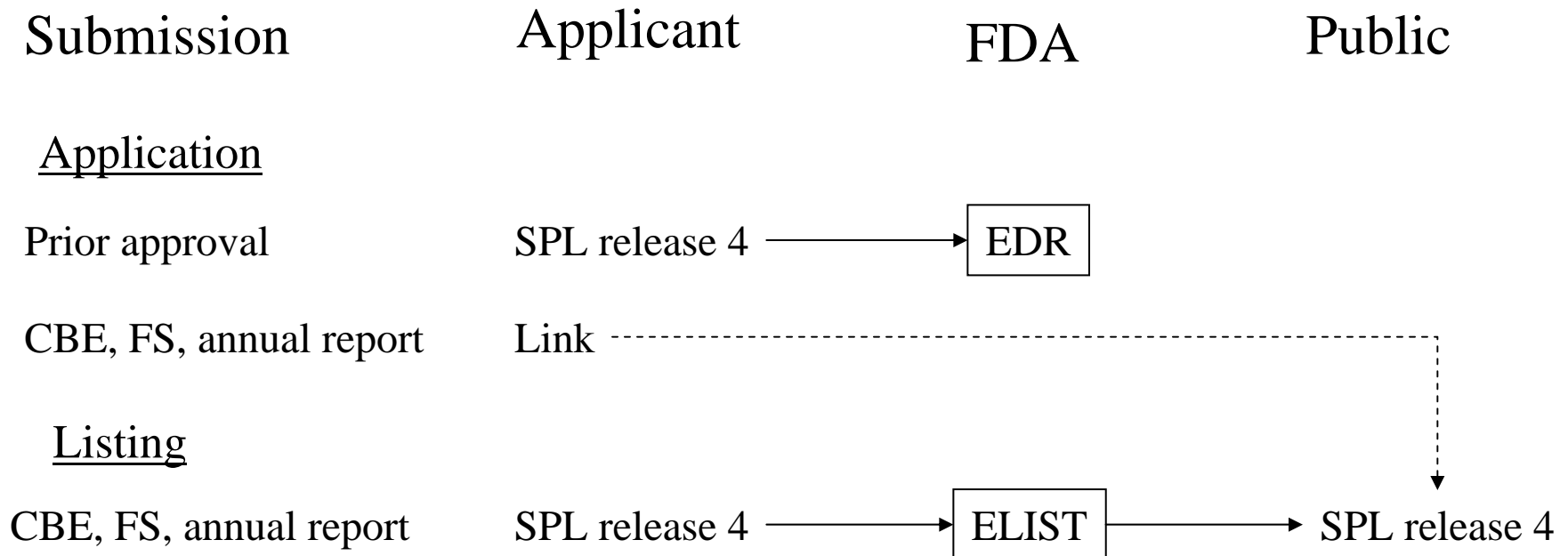
Listing an Approved Drug Regulated by CBER & CDER

- eList system
 - key repository for currently used content of labeling in SPL format. (as of June 1, 2009)
 - Utilized to transmit SPL to DailyMed
 - Replaced ELIPS system

SPL Submission for Application Product Listing in Electronic Format



Application Product Listing in Electronic Format with Link to Posted SPL file (when file submitted via eListing Process)



Referencing “Application Product” SPL

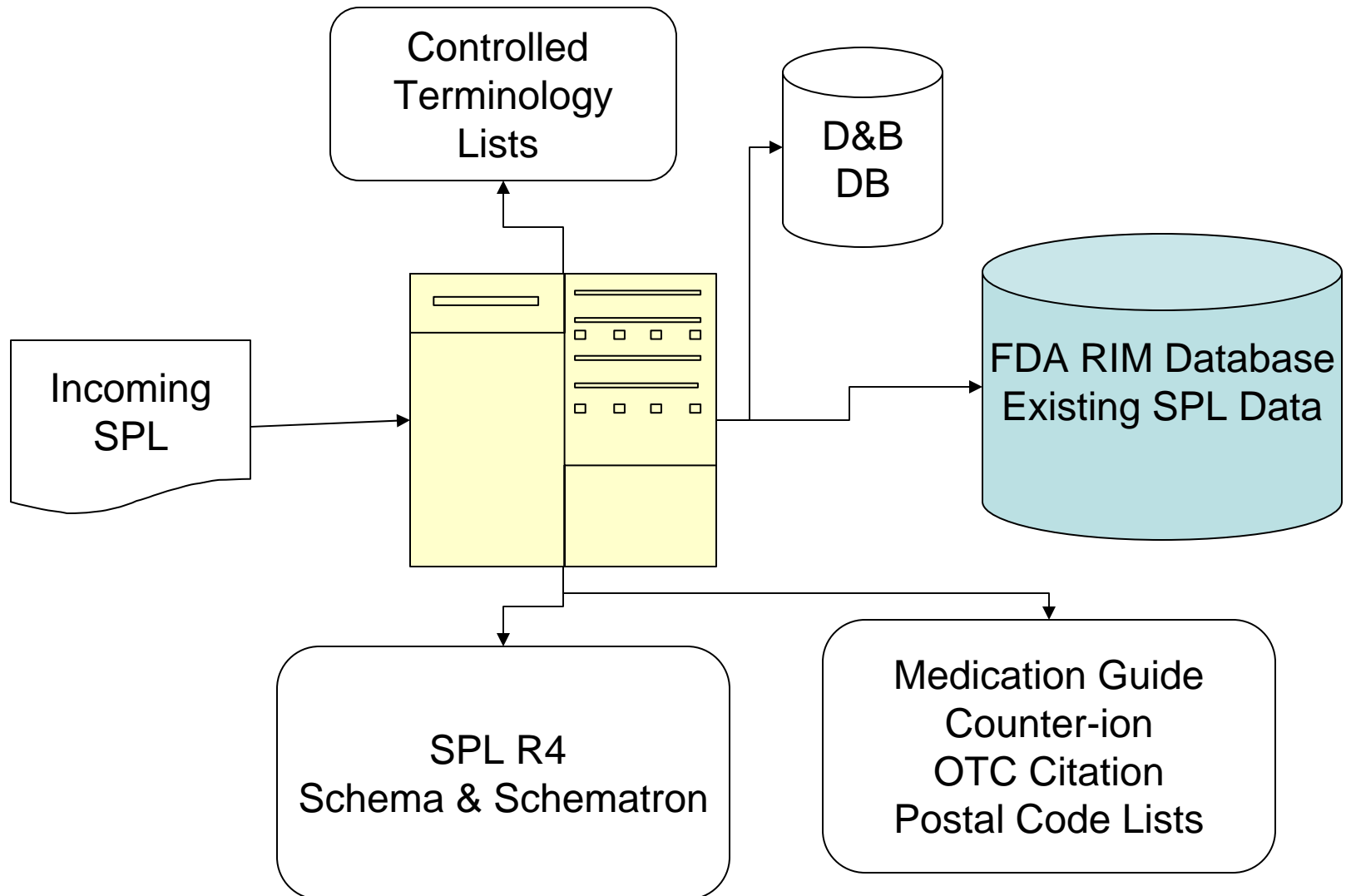
- Referencing the identical content of labeling submitted during listing process
- Include a statement and hyperlink in your application submission
- (e.g., “We have submitted the SPL file with drug listing; it can be found at the following location <http://www.accessdata.fda.gov/spl/data/> [*insert your SPL document id root here/insert SPL document id root here*].xml”]

Validating SPL Documents

Validation

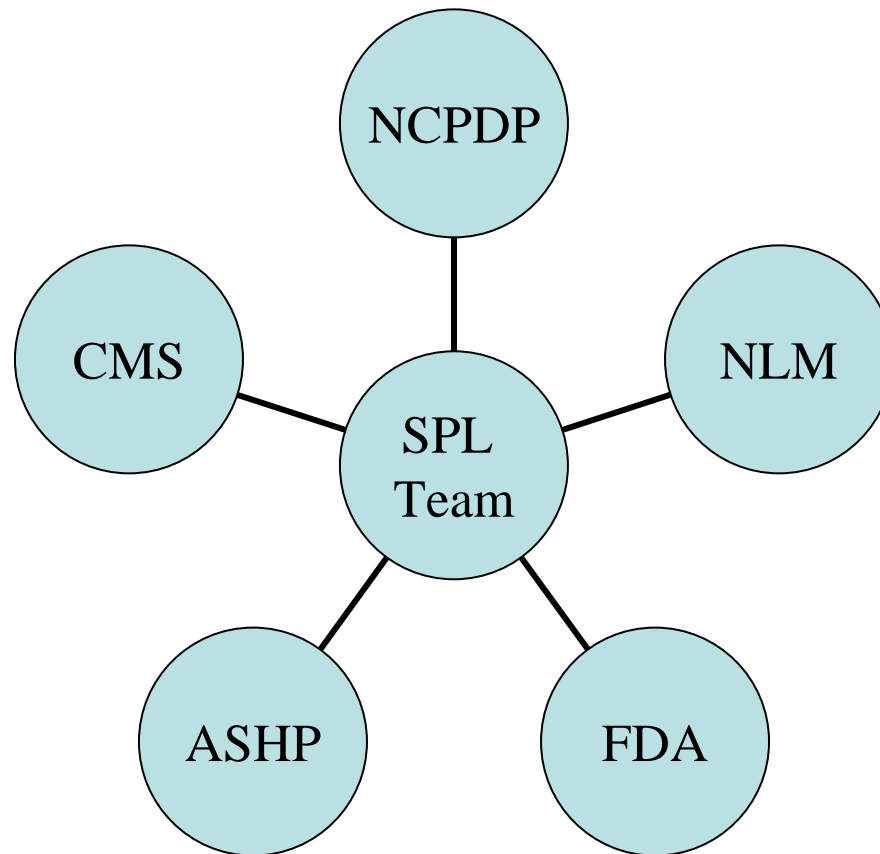
- Based on Schematron technology
- Pragmatic Data Validator Lite – detects 95% of errors. Is not connected to FDA's database
- Utilization of training documentation will assist in the avoidance of many validation errors
- Implementation of new validation procedures will occur we strive to improve the automated system
- No automatic validation of SPL documents submitted directly to application

Validation Model



Another Validation Method

Sources of Feedback



Common Errors in SPL Data

- Wrong active ingredient – active moiety relationship
- Active Ingredient/Active Moiety Relationship list
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm169455.htm>
- Incorrect basis of strength (active ingredient instead of active moiety)
- Wrong unit of measure for strength (e.g. 100 **micrograms** instead of 100 **milligrams**)
- Wrong dosage form (e.g. ointment instead of gel)

Validation Error Notifications

- Transmitted via FDA Gateway to submitter
- Transmissions occur within 36 hours (business days)
- In the form of a 2nd or 3rd acknowledgment
 - 2nd acknowledgment – system-generated message
 - 3rd acknowledgment – manually generated message with additional notes
- No 2nd or 3rd acknowledgment within 24 hours usually denotes that submission was accepted

Additional Validation Lists

- Counter-ion – determines if an active moiety is entered in active moiety field
- Future: Active Ingredient/Active Moiety
- Postal Code – Validates that zip code is entered for countries with postal code systems
- OTC Monograph Regulatory Citations – determines entry of permissible OTC regulatory citations

Product Data Element Errors

- Product data elements in SPL versions can be corrected.
- Expected error: *“If the NDC Product Code was previously submitted, then the product and generic name, active ingredient UNII, dosage form, active ingredient strength, product characteristics of size, shape, color and imprint code must be the same as in the most recent submission for this NDC code.”*
- Request manual override of system – Submit Gateway core ID to spl@fda.hhs.gov with reason for alteration of data elements
- Response to manual override ONLY if request is NOT granted.

Questions Regarding Errors

- Send Gateway **core ID** to spl@fda.hhs.gov
- Common Error Monthly Update –via HL7 SPL Working Group
 - Interpretation of common errors
 - SPL Training eBook # 14 Common Technical Errors

SPL Training Tools

- SPL Training eBooks and eCards
<http://spl-work-group.wikispaces.com/SPL+eBooks+-+Graphic+Guides>
- Suggestions for training tools? – contact spl@fda.hhs.gov with your suggestions

SPL Lifecycle Management

Accomplishments

General SPL Topics

SPL Lifecycle Management

- Lifecycle management is now controlled by SPL authors
- Proper management of your document's setID is very critical.
- Once you submit each SPL with a setID, you should ensure that you use that setID in all updates of that document (including R3 SPL documents)

Accomplishments

- FDA has been using the SPL standard for almost 6 years (CDER ~ 6 years, CBER ~ 3 years, CVM ~ 2.5 years)
- DailyMed –
 - over **10 million** visits per month
- Unique SPL documents posted on DailyMed
 - **March 2012 – almost 35,000**

HL7 SPL WG

- The HL7 SPL Implementation Workgroup meets regularly to discuss the implementation of SPL
- Members
 - Pharmaceutical industry
 - Academia
 - HL7
 - FDA
 - SPL developers/vendors
- Membership in HL7 is not required to participate.
- See bottom of this web page:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Stay Informed

- Join FDA Data Standards Council listserv
- <http://www.fda.gov/ForIndustry/DataStandards/default.htm>



The screenshot shows the FDA Data Standards Council website. At the top is the U.S. Department of Health & Human Services header with the www.hhs.gov URL. Below is the FDA U.S. Food and Drug Administration logo and a search bar. A navigation bar lists various FDA categories. The 'For Industry' section is highlighted, with a breadcrumb trail: Home > For Industry > Data Standards. On the left is a 'Data Standards' sidebar menu with links to Validators, Data Council, Structured Product Labeling, Individual Case Safety Reports, and Regulated Product Submission. The main content area is titled 'FDA Resources for Standards' and features a 'Sign up for email updates.' link with an arrow pointing to it. Below this is a paragraph about the council's role and a link to 'Structured Product Labeling'.

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration

A-Z Index Search go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

For Industry Email this page Print this page Change Font Size

Home > For Industry > Data Standards

Data Standards

- Validators
- Data Council
- Structured Product Labeling
- Individual Case Safety Reports
- Regulated Product Submission

FDA Resources for Standards

 Sign up for email updates. ←

The FDA Data Standards Council coordinates the evaluation, development, maintenance, and adoption of health and regulatory data standards to ensure that common data standards are used throughout the agency.

[Structured Product Labeling](#)

SPL-related Questions

- SPL e-mail account (spl@fda.hhs.gov)

QUESTIONS?

Thank You